MEDIMOP
MEDICAL PROJECTS LTD.

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NOV - 3 2006

510(k) summary for the VENTED VIAL ADAPTER TRANSFER DEVICE

(as required by section 807.92)

510(k) Notification submitted by:	Medimop Medical Projects Ltd. 17 Hatidhar St. P.O. Box 2499 Ra'anana 43665 Israel Phone: + 972 (9) 7757122 Fax: +972 (9) 7485916
Contact person:	Ari Y. Sobel Director, Quality and Regulatory Affairs
Date Summary Prepared	July 18, 2006
Trade Name:	Vented Vial Adapter Transfer Device
Classification name:	General Hospital Class II, 80LHI Per 21 CFR 880.5440 Intravascular administration set
Common device name:	Same as Trade name
Predicate devices:	MIXJECT® DISPENSING PIN 510(k) No. K963583 Medimop Medical Projects Ltd. MIXJECT® DISPENSING PIN 510(k) No. K001293 Medimop Medical Projects Ltd. MIX2VIAL TRANSFER DEVICE 510(k) No. K031861 Medimop Medical Projects Ltd. CHEMO MINI SPIKE PLUS 510(k) No. K983794 B. Braun Incorporated TAKY SPIKE PLUS 510(k) No. K974198 Clinico
Manufacturer:	Medimop Medical Projects Ltd. 17 Hatidhar St. P.O. Box 2499 Ra'anana 43665 Israel

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Material:

The Vented Vial Adapter Transfer Device is composed of materials that were tested in accordance with the ISO 10993-1 standard and/or USP VI requirements and were determined suitable for the Indications for Use of this product.

Device Description:

The Vented Vial Adapter Transfer Device is designed for the purpose of allowing safe and easy transfer of liquid drugs from and into vials while keeping the process in pressure equilibrium with the ambient pressure. The product allows quick transfer of the contents of a syringe, typically containing diluents, into a drug (in the form of powder) vial and easy aspiration of the dissolved drug back into a syringe, or any other standard accessory.

The Vented Vial Adapter Transfer Device is an assembly of three components. A Hydrophobic medium (optional) is attached to the "body" with the double lumen spike (penetrating the rubber stopper) and a cap (with a luer connection) is attached to the sub-assembly.

Indications for Use:

The Vented Vial Adapter Transfer Device is intended for the transfer and mixing of drugs contained in vials.

Technological comparison to Predicate Device:

The Vented Vial Adapter Transfer Device has Indications for Use similar to the predicate devices – all are intended for transferring and mixing drugs and diluents contained in vials. All products have piercing spikes, which enable the users to create a direct passage to and from vials, in a sterile manner.

The Vented Vial Adapter Transfer Device allows the connection any standard accessory with a luer connection to be connected to a vial. Once mixing of the diluent and the drug is complete the drug solution is ready for use and may be aspirated into an accessory (e.g. syringe). This is similar to Medimop's Mixject dispensing pin (K963583). The adapter vial assembly is a single use device and should be disposed of after use.

All devices are packaged sterile and designed ergonomically. A filter may be included, so as to assure purity of the dissolved drug prior to its injection.

Any differences between the Vented Vial Adapter Transfer Device solution and the equivalent devices have no significant influence on safety or effectiveness.

Safety and Effectiveness:

All finished products are tested and must meet all required release specifications prior to distribution. The array of testing required for release include but are not limited to; Physical testing, visual examination (in-process and finished product).

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Conclusion:

It is our conclusion that the Vented Vial Adapter Transfer Device and its predicates are substantially equivalent in their Indications for Use, design, material, sterility and packaging.

The Vented Vial Adapter Transfer Device is to be used in a similar manner to the predicate devices and introduces no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ari Y. Sobel
Director, Quality & Regulatory Affairs
Medimop Medical Projects, Limited
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ISRAEL

NOV - 3 2006

Re: K062482
Trade/Device Name: Vented Vial Adapter Transfer Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: August 15, 2006
Received: August 24, 2006

Dear Mr. Sobel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ___ _____ __

Device Name: Vented Vial Adapter Transfer Device

Indications for Use: Transfer and Mixing of drugs contained in vials

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible] of Anesthesiology, General Hospital, [illegible] Control, Dental Devices

[illegible]: K062482